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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/031,629	02/27/1998	DENISE FAUSTMAN	11275/73537	8880

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EXAMINER	
NOLAN, PATRICK J	
ART UNIT	**PAPER NUMBER**
1644	29

DATE MAILED: 07/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/031,629	Faustman et al.
Examiner	**Art Unit**
Patrick J. Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 22, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *65-71* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *65-71* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Part III DETAILED ACTION

1. Claims 65-71 are pending.

2. The request filed on 4-22-02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/031,629 is acceptable and a CPA has been established. An action on the CPA follows.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 65-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting IDDM by detecting a reduction in the proteolytic processing of NfκB by proteosomes, does not reasonably provide enablement for detecting any autoimmune disease by detecting a reduction in the proteolytic processing of NfκB by proteosomes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

The specification discloses only one working example demonstrating the ability of detecting a reduction in the proteolytic processing of NfκB by proteosomes and correlating said reduction with an autoimmune disease. The state of the art, The Merck Manual of Diagnosis and Therapy, does not recognize the use of detecting a reduction in the proteolytic processing of NfκB by proteosomes for detecting all of the myriad amount of autoimmune diseases. In addition the Merck Manual teaches there are five independent possible mechanisms for developing an immune response to autoantigens. Lahita et al., specifically teaches that even within the NOD mouse that IDDM disease is not a certainty, in fact the range of disease frequency is 20-80%, and depends upon environmental factors since all NOD mice represent the same inbred strain. Applicant's specification discloses that the NOD mouse is predictive of all autoimmune disease because the same defect in NOD mice occurs in all autoimmune diseases. However, even within IDDM there are at least 14 genetic loci that have been linked to the development of the disease. For Applicant to state that a single unifying molecular event is common to all forms of autoimmune diseases is not supported by the state of the art, especially in light of the fact that not all genetically predisposed NOD mice get

IDDM. The state of the art clearly recognizes that genetic malformations alone are not sufficient for consisting developing an autoimmune disease, specifically, IDDM, as represented by the NOD mouse. Since the breadth of Applicant's claims reads upon at least 60 recognized autoimmune disorders and their is no specific guidance or working examples to enable one of skill in the art to reasonably predict that detecting a reduction in the proteolytic processing of NfκB by proteosomes would correlate to a wide range of autoimmune disorders and the state of art as taught by The Merck Manual does not recognize the use of said detection method, it would be unpredictable and require an undue amount of experimentation to practice the full scope of Applicant's claimed invention.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

5. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
July 3, 2002